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Physical Simulation Training Model for Suturing of Blood Vessels.

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Physical Simulation Training Model for Suturing Blood Vessels

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***Abstract*—The purpose of this project is to design a higher fidelity physical simulation training model for suturing of blood vessels, specifically in the case of a femoral-popliteal artery bypass. The main improvements introduced to this model include a pump to simulate continuous blood flow and a more realistic housing apparatus, which lead to an overall more life-like surgical setting. An additional goal of this project is to implement cheap, easily replaceable parts in the model that allow for greater continued use of the training model. To accomplish this, some compromises were made with the chosen tubing that sacrificed realistic properties for price and availability. The intention of the final product is to better train surgeons to improve overall performance and success rate when transferring the skills gained from simulation to actual surgery.**

I. Introduction

Diseases associated with arteries are referred to as peripheral arterial disease (PAD). These are usually associated with blocked arteries in the legs due to atherosclerosis, or a small fatty tissue that has blocked off the inside walls of an artery. PAD is a greater risk to the elderly, especially males over 65. This blockage causes a decrease in blood flow to the lower leg, which depletes the amount of nutrients and oxygen provided. Femoral and popliteal arteries are the most common locations for atherosclerotic disease to develop, and its presence is usually an indication of more serious problems, such as atherosclerosis in the brain and heart.

Peripheral arterial diseases can be present without any developed symptoms. In more severe cases, pain and ulcers are prevalent. Most severe cases, called critical limb ischemia, can cause constant pain and lead to amputation of the limb. In order to avoid such severe complications, femoral popliteal bypass surgeries are recommended for treatments of most peripheral arterial diseases before severe complications.

The actual femoral popliteal bypass procedure inserts a shunt into the lower leg that will circumvent the blocked artery. The bypass is attached above and below the blockage. The shunt used is usually the femoral vein to avoid any further complications that could be associated with rejections of the bypass by the body. In some circumstances, an artificial graft such as Gore-tex can be used. Although risk of complication is factor in any procedure, this surgery is the only effective treatment to prevent further degradation of the lower leg; therefore, the benefits outweigh the risks when considering treatments for PAD.

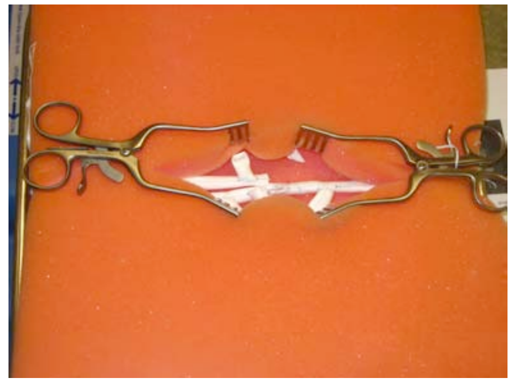

Figure 1: Previous Model

The current model used to train surgeons to treat PAD is a very rudimentary design that concentrates on teaching surgeons to suture vessels and ignores all other aspects of a femoral popliteal bypass. The design, seen in Figure 1, is composed of two flat foam pieces that are clamped on the edges with a piece of tubing running through the middle. The top foam piece contains a straight opening to simulate the cut in the leg that would be made in real surgery.

As seen in Figure 1, the tubing used in this model is Gore-tex elastic tubing, patent number 5716395. This tubing has been designed with medical applications in mind, specifically being implemented as shunts for bypass surgeries that involve peripheral arterial diseases. The properties of this tubing are closely related to properties of actual arteries making this tubing an ideal substitute for lab simulations. In addition, since this tubing can also be used in some circumstances as the shunt instead of patients' own veins, becoming familiar with Gore-tex tubing is beneficial to surgeons. Because of the similarities Gore-tex shares with real arteries, it is very expensive to purchase in bulk. This means multiple simulations have to be run on the same piece of tubing that will decrease the quality of the tubing and the quality of the simulation itself.

The rest of the simulation model only further removes the surgeon from the setting of a real surgery. The model does not resemble a leg; therefore, no pre-surgery techniques can be practiced. There is no flow throughout the process, so clamping is not practiced. Tunneling procedure, which may be used in real surgery, is also skipped. The model used is very simplistic and easy to replace, but serves only to teach surgeons to suture vessels together.

The model that was designed for this project improves the shortcomings of the original model. The main areas of concentration for improvements were the model casing, skin, tissue, pumping system, and vessels. Although finding cheap realistic tubing was a goal for this project, it was less important since the tubing could always be replaced with Gore-tex for a more realistic simulation of vessels. The final design will allow surgeons to practice a femoral popliteal bypass procedure under more realistic conditions to better prepare them for actual practice.

II. Materials

A. Mannequin Leg

The casing used to house the new model was a department store mannequin leg. This leg was donated from *Classy Lady*, a women's department store. Therefore, it was representative of a slender, female leg and was atypical of an average patient presenting with PAD. The mannequin leg was hollow with a hard outer casing, making it an ideal housing for this model. Due to the hard outer shell, it was necessary to have pre-cut holes to allow the surgeons access to the vessels. This limits the work area available to the surgeons for the procedure. However, the casing now more realistically resembles a leg and will not need to be replaced for some time.

B. Skin

The skin material used in the final design was a bilayer of iodine wrap with Polytek PlatSil Gel. Including a layer of skin in the final model greatly contributed to the tactile and visual authenticity. A layer of skin was covering one of the openings in the mannequin leg to better simulate the surgical incision, as well as the difficulty in keeping the incision spread open. Because the skin was permanent, it was necessary to pre-cut the skin prior to the procedure, which took away from the realistic feel of an initial incision. The initial incision would allow for the surgeons to determine the location, orientation, depth, as well as the physical act of cutting through the skin, all of which was lost with a pre-cut design.

C. Tissue

The tissue material used in this model was an enhanced version from the previous design. Several large grouting sponges were used to make up a majority of the inside of the model. The sponges were cut to fit the shape of the leg. On the bottom of the model, precut sponges were permanently secured. Additional grouting sponges were placed superiorly to the permanent sponges. These sponges were pre-cut to accommodate the placement of the artery and surrounding vessels and were sprayed with cooking oil to more accurately simulate flesh. However, a slippery sponge was not the most accurate simulation for flesh. The non-permanent sponges were easily and cheaply replaced, allowing for extensive use of the model.

D. Vessels

The primary focus of the simulation was the artery. The material used for the artery was Cole Parmer peroxide cured silicone tubing. Similar to the average femoral artery, the dimensions of the arterial tubing used were 0.25" inner diameter and 0.3125" outer diameter. The silicone tubing was appropriate for this simulation because it is soft, flexible, and resealable when punctured. It was also very affordable and easily obtained in large quantities, allowing for each surgeon to train on a new artery. Although the artery was relatively thin, it was thicker than an actual artery and did not collapse upon itself, which took away from the realistic properties of a femoral artery. To provide landmarks for a more realistic design, two other vessels were included in the model. These were represented by a blue and white balloon, simulating the femoral vein and nerve, respectively. Although these do not accurately represent the physical properties and dimension of the vessels they were simulating, they serve primarily as landmarks to increase the visual layout of the model. The lymphatic vessel was omitted from the final design due to limited space.

E. Piping

The rubber hosing used for connecting the vessels to pump, minimizing the use of the more expensive tubing, was 0.375" outer diameter by 0.25" inner diameter latex rubber tubing, purchased at Home Depot. To connect this tubing to the tubing used for the vessels, 0.25" x 0.25" connectors were used. A 0.25" x 0.25" x 0.25" splitter was used to create a bypass, to accommodate the clamping of the vessels during simulation. A ten gallon Rubbermaid tub, purchased at Wal-Mart, was used as the reservoir to allow for continuous flow.

F. Pump

A Welco WP-1000 was obtained at no charge from the Welco Corporation. The pump is a peristaltic pump, which pulses in a similar manner to blood flow in the peripheral vessels. Two nine volt batteries were used to power the pump, giving a total of 18 volts. A black project box, purchased from Radioshack, is used to house the pump, batteries, and a power switch, as well as all of the connecting wires.

III. Procedure

Handling the mannequin leg was the first step in assembling the model. The structure of the leg was the foundation upon which all other materials were added. The Senior Instrument Designer, Daniel Graham, was recruited to cut the leg according to specifications. These specifications included bifurcation along the longitudinal axis as well as openings in the thigh and lower leg. The previous openings were based on surgical observations and discussions with medical professionals.

Following the modifications to the mannequin leg, pre-cut sponges were permanently affixed to the base of the model. These sponges were pre-cut to accommodate the dimensions of the leg. Another set of pre-cut, non-permanent sponges were used for accessibility to necessary vessels as well as easy replacement. The pre-cut, non-permanent sponges were cut in such a way that vessels could be placed within the center of the leg in accordance with the anatomical positions.

After careful consideration a bi-layer skin design was utilized to simulate skin. This bi-layer design consisted of first a layer of iodine wrap placed directly onto the mannequin leg. On top of this was a three step skin formula, Polytek PlatSil Gel, which was applied in two coats for a thicker layer. The final application was another layer of iodine wrap to seal and prevent wear on the Gel. On the upper thigh of the mannequin leg, the opening was covered with a layer of the skin. This skin was then cut to simulate the actual procedure of folding back the skin after the first incision. The skin covering the opening on the lower leg was removed due to complications with the properties of the mannequin leg.

In order to power the pump, solder and electrical tape were used to connect the batteries, pump, and switch to each other. The black project box was cut to allow the pump and switch to sit inside.

Figure 2: Flow Design

As seen in *Figure 2,* a continuous flow design was utilized in this model. The continuous flow was created first by utilizing a reservoir, which was connected to the pump via latex rubber tubing. The flow continued out of the pump through more latex rubber tubing, where it then met a splitter. One output of the splitter ran through the leg using the peroxide cured silicone tubing, while the other output went back to the reservoir using the latex rubber tubing. The peroxide cured silicone tubing ran through the leg to a connector. From this connector, latex rubber tubing was used to connect the flow back to the reservoir, completing circulation.

IV. Analysis

A. Mannequin Leg

Because the average person afflicted with PAD is an overweight, elderly male, a female mannequin leg was not the most accurate representation for the model. In addition, the rigid shell of the leg limited the surgeon's ability to tunnel from the lower to upper leg. This rigidity also detracted from the realistic feel of the model.

B. Skin

Before deciding upon the bi-layer skin design, a costume plaster modeling kit was tested. The results from these tests yielded an unusable, brittle material. The final skin design was superior to the plaster modeling kit due to its tactile feel.

C. Tissue

One of the primary improvements upon the previous design was a more realistic tissue. Several ideas were considered. Making the tissue entirely out of ballistics gel was the first proposed idea. However, difficulties in storing and casting the ballistics gel proved this idea to be unreasonable and expensive. The next idea was to soak the grouting sponges in gelatin. After numerous trials of varying concentrations and volumes of gelatin mix, it was determined that this design was also unreasonable. This was due to the difficulty in obtaining an even gradient and life-like compressibility of the sponge. The final design was a sponge sprayed with cooking oil. This simulates the tactile sensation and compressibility of real tissue while remaining affordable and replaceable.

D. Vessels

After researching the dimensions of an actual femoral artery, dozens of sample tubes were obtained. The final tubing chosen for the model was the softest tubing that was available with the most accurate dimensions. In addition, this tubing was able to reseal upon itself after being punctured. This was a crucial characteristic for the vessel because the suturing of blood vessels was the primary objective of the simulation. Many of the sample tubes were either too rigid or were too thick. This was due to the fact that the tubes were intended for medical pumps rather than medical simulation. These companies were contacted because their products were substantially cheaper and more readily available than medical simulation tubing.

Although the tubing obtained detracts from the overall realism of the model, this sacrifice was necessary to improve the overall learning experience. Because of the availability and price of the chosen tubing, it was now possible for each surgical resident to practice on an unused segment of the vessel. As opposed to the previous model, which uses the more expensive and harder to obtain medical simulation tubing, the surgical residents will not be required to use the same segment repeatedly.

E. Flow

The pump pulls water from the reservoir, which is located closely below the model. This proximity is due to the fact that the pump used was relatively weak. Several tests were run to determine the optimal voltage to power the pump. These tests included running batteries in parallel, series, and a combination of the two. The results from these tests showed that the optimal design was two nine volt batteries in series. The pulse rate of the pump was observed at 160 pulses per minute. Although this rate is much faster than a heart rate during surgery, the pulses are not strong enough to detract from the overall surgical simulation.

The flow of the design begins in the reservoir located beneath the leg. The pump pulls water from the reservoir vertically to allow for level flow through the leg. A connection was made between the rubber tubing and pump tubing via a two piece connector. The tubing flowing out of the pump was also connected to another set of rubber tubing via a similar two piece connector. The next connector in the design was a three-way splitter placed at a specific angle allowing for the bypass to be nearly vertical. This prevents flow through the bypass when there was no clamping down stream. The pressure was not sufficient enough to overcome the vertical head of the bypass tubing. The three-way splitter also connected to the peroxide cured silicone tubing located within the leg for the actual suturing procedure. On the distal end of the leg there was another two piece connector attaching the rubber tubing with the silicone tubing. The final rubber tubing returns the flow back to the reservoir for a recycling of water effect.

V. Discussion

A. Improvements to the Previous Model

The final design incorporated improvements on the previous design in various areas. The first area of improvement was the inclusion of a mannequin leg to house the rest of the model. The previous design, as seen in *Figure 1*, included no leg. The visual stimulus of the mannequin leg added to the overall authenticity of the training simulation.

The addition of a leg used as the housing provided the opportunity to add a layer of skin. The skin created a more realistic visual and tactile experience. Again, the previous design did not contain this aspect of materials.

Although the material used for tissue was very similar to the previous design, improvements were made. Most notably, among these, was the easy replaceability of the grouting sponges. This allows for an easy replacement of worn out, used sponges. Also this provides the ability to include tunneling into the simulation. Tunneling is the process by which a surgeon can force the bypass tube from one suturing site to the other site through the fascia. Another added improvement upon the previous model is the addition of cooking oil. Because the final design was much more constricted than the previous design, an addition of oil can affect the simulation. Had this been added to the previous design the affect would have been lost on the large open space.

Tubing used for the final design was an improvement upon the previous design due to multiple reasons. The first advantage was the addition of veins and nerves which provide for anatomical accuracy. These vessels will serve as guides for surgeons preventing from making mistakes. The actual tubing which was used was much easier obtained as well as relatively inexpensive.

By integrating a pump into the final design, continuous flow was then possible. In the previous design, flow was simulated manually via a syringe. This process was only utilized to ensure a complete seal during the suturing procedure. The affect of a continuous flow created a more realistic simulation forcing the surgeons to practice clamping while also providing a quick test for a complete seal.

B. Possible Improvements to the Final Model

The Mannequin leg acquired for the final design was not an accurate representation of the average individual who must undergo such a procedure. The leg more accurately represents a slender female leg, as opposed to an overweight, elderly male. A possible improvement would be to acquire a more accurate leg. If possible, better improvements could be made to the material used for the tissue. Alternative ideas were either unfeasible or too expensive. The tubing used for the final design of the artery was not an ideal representation. If a Gore-tex like material had been found at a reasonable price, it would have been a better fit for the model. However, if such tubing is found at a later time, the model can be easily adapted to include this type of tubing. A stronger pump would have been preferred. The current model does not allow any control of pulsing and rate of flow. Also a timing apparatus could be added allowing for the inclusion of metrics.

The overall final design, met the objectives of creating a more realistic simulation environment. While there is room for improvement, this design is a marked improvement upon the previous design.

VI. Acknowledgements

We would like to thank the following individuals for their support during our design process: MABE office staff, Mr. Daniel Graham, CST Judy Roark, April McMillan, Kara Krus, Dr. Jack Wasserman, and Dr. William Hamel.

VII. References

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Physical Simulation Training Model for Suturing of Blood Vessels

Advisors: ORNL: Kara Kruse, April McMillan; UTK: Dr. William Hamel, Dr. Jack Wasserman; UTK med: CST Judy Roark

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Presenters: Alexander Bada, Aleksandr Birg, Abigail Henson, Abhinav Narain, Carly Nye, Nathan Summers, James Weismiller

Objective

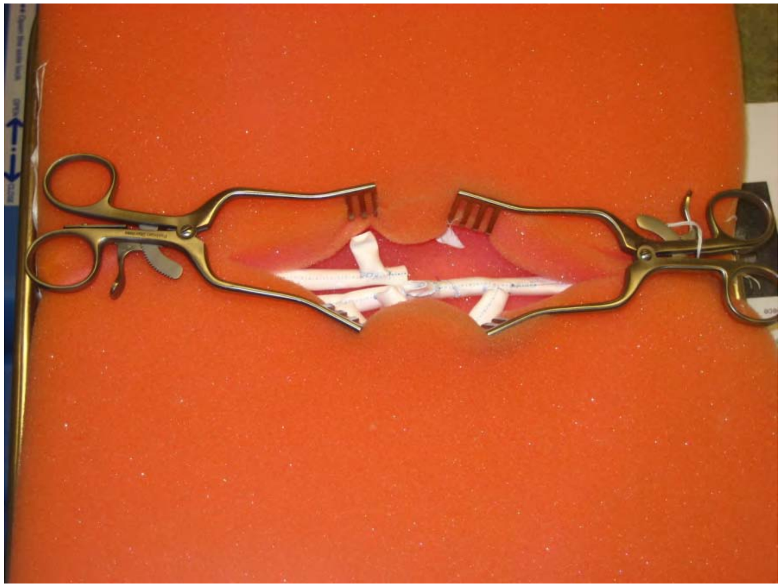
- Create a more realistic simulation training model to be used as a teaching device for University of Tennessee Medical School Residents. The model will be life-like in material and flow, and imitate surgery conditions. The model will also be inexpensive and replaceable.

Overview

- Previous Design
- Final Design
- Materials
  - Leg
  - Tissue
  - Skin
  - Vessels
- Pump Flow
  - Pump
  - Pulsing
- Improvements
- Finance
- Questions

Previous Design

- Materials
  - Foam-tissue
  - Metal tray
  - Gore-Tex vessels
- Flow
  - No flow
  - Syringe



Final Design

- Materials
- Pump Flow

Materials

- Leg
- Tissue
- Skin
- Vessels

Leg

- Proposed
  - Foam Core
  - Create a Mold
  - Mannequin
- Chosen
  - Mannequin

Leg Continued

- Advantages
  - Free
  - Manipulative
  - Solid
- Disadvantages
  - Rigid
  - Texture
  - Female

Tissue

- Proposed
  - Ballistics Gel
  - Kapoosh ©
  - Foam
    - With Cooking Oil
    - With Gelatin
    - Alone
- Chosen
  - Foam
  - Cooking Oil

Tissue Continued

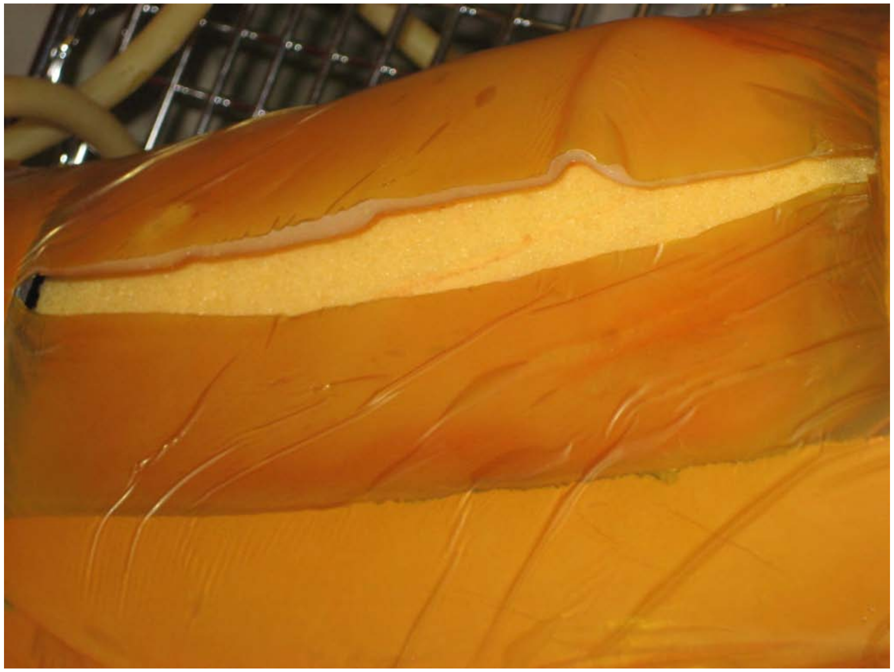
- Advantages
  - Slippery
  - Compressible
  - Inexpensive
  - Replaceable
- Disadvantages
  - Life-like
    - Appearance
    - Feel

Skin

- Proposed
  - Iodine Wrap
  - Latex
  - Saran Wrap
  - Alja-Safe Molding Gel™
  - Polytek Platsil Gel ®
- Chosen
  - Iodine Wrap
  - Polytek PlatSil Gel ®
    - 3 step process

Skin Continued

- Advantages
  - Soft
  - Compressible
  - Realistic Feel
  - Permanent
  - Inexpensive
- Disadvantages
  - Pre-cut

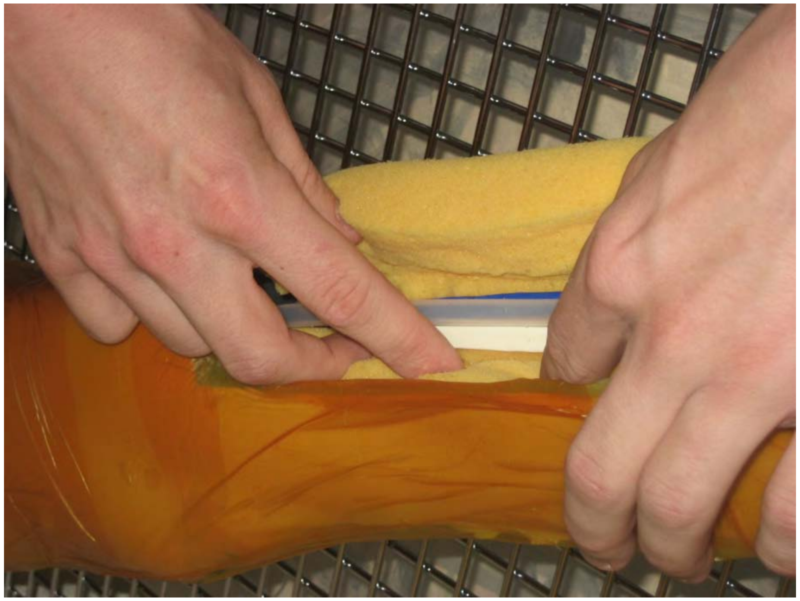


Vessels

- Proposed
  - Silastics
  - Gore-Tex
  - Foley Catheter
  - Balloons
  - Rubber Bands
  - Pump Tubing
    - Cole Parmer
    - Master Flex Tubing Kit
    - Davis Instruments
- Chosen
  - Balloons
    - Veins and Nerves
  - Cole Parmer
    - Artery
      - Silicone (Peroxide Cured)

Vessels Continued

- Advantages
  - Size (1/4” x 5/16”)
  - Market
  - Inexpensive
  - Replaceable
  - Resealable
- Disadvantages
  - Not Collapsible
  - Clear
  - Thick Walls

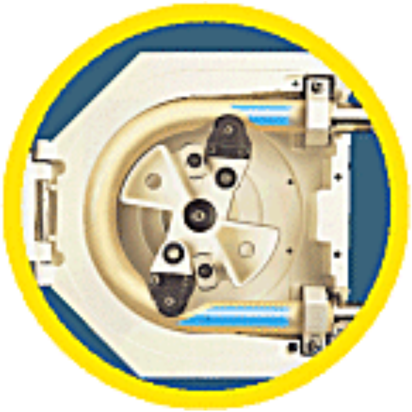


Pump Flow

- Pump
  - Welco WP-1000
  - Mechanics
  - Implementation
- Flow
  - Reroute backflow
- Pulsing
  - Materials
  - Mechanics
  - Implementation

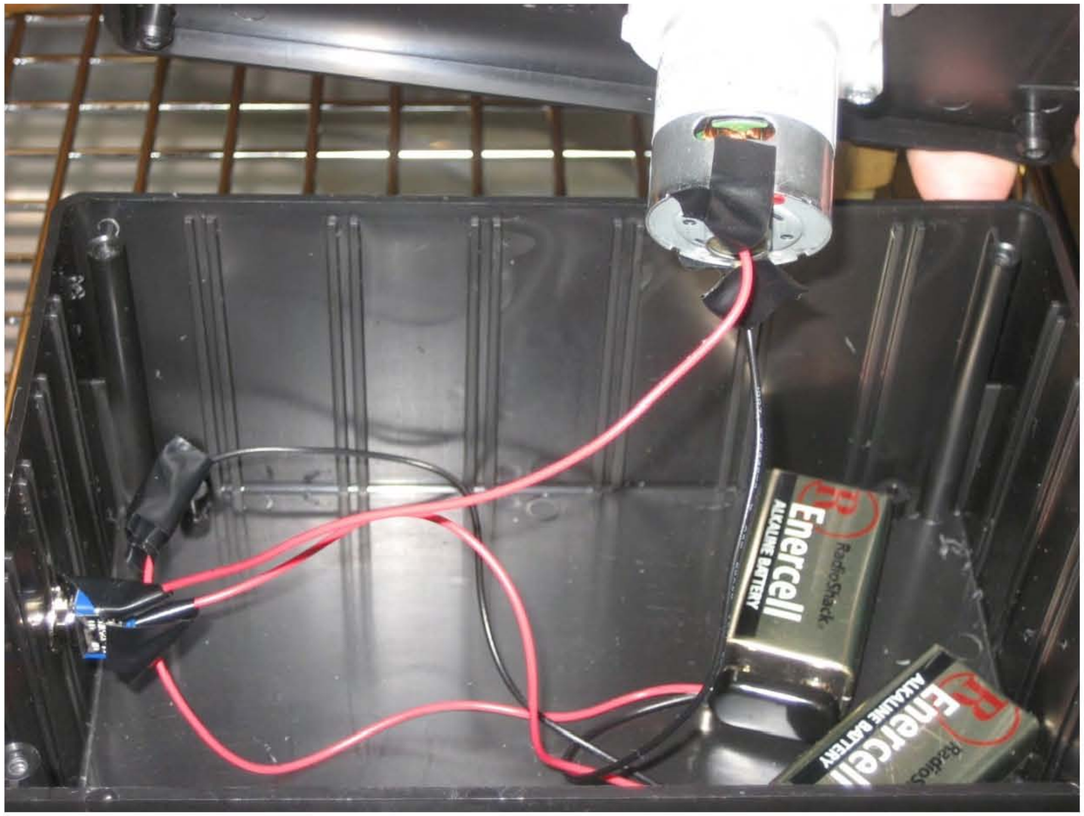
Welco Peristaltic Tubing Pump

- WP-1000
  - Output: up to 600 mL/min
  - ID x OD Tube Size: 1/4” x 3/8”
  - Actual Voltage: DC 18 V
  - Tube type: Pharmed
- Reservoir
  - Continuous Flow
  - Stop Backflow



Pump

- Disadvantages
  - Speed
  - Power



Flow

- Circular Flow
  - All Tubing (ID 1/4")
  - Reservoir
- Rerouting
  - 3-way splitter

Flow Continued

- Advantages
  - Simplistic
  - Prevents Backflow
  - Continuous
- Disadvantages
  - Bulky
  - Position

Pulsing

- Proposed
  - Solenoid Valve
    - Circuit Controlled
  - Hand Pump
  - WP-1000 Pump
- Chosen
  - WP-1000 Pump
    - 160 bpm
    - Implemented Batteries

Pulsing Continued

- Advantages
  - Real Pulse
- Disadvantage
  - Speed
  - Volume
    - 0.28 L/min

Improvements

- Tissue
- Testing
- Tubing
- Leg

Finances

- Final Design Total Cost
  - Approximately $340
- Replacement Cost
  - Approximately $25
    - Battery Replacement
    - Tissue Replacement
- Supplies Cost
  - Approximately $25
- Experimental Cost
  - Approximately $60
- Total Spent
  - Approximately $450

Questions